

Structured Product Labeling (SPL) OTC Sub-team Teleconference

Monday, January 12, 2009, 1:00 pm – 2:30 pm ET

Call Summary

I. Welcome and Introductions

Call included approximately 40 SPL OTC sub-team members and guests.

II. Next Standing Teleconference: January 26, 2009 (**extended call**: Glemser Technologies presentation)

III. Mass Delisting Procedures – see below. Lonnie Smith (FDA) advised the date for discontinuation should be the date the product will no longer be used.

IV. January 8, 2009, [Federal Register](#) notice

Please let sub-team co-leaders [Paula Markert](#) (GSK) and [Devon Morgan](#) (Perrigo), and [Marcia Howard](#) (CHPA) know if as soon as possible if additional comments should be submitted on behalf of the sub-team. Comments originally submitted by the sub-team can be viewed at: http://www.chpa-info.org/media/resources/r_5258.pdf.

Individual companies are encouraged to make their own submission as deemed necessary.

V. Upcoming SPL Educational Forums

- A. i4i webinar (today)
- B. Glemser Technologies webinar (January 26, 1:00 -2:30 pm ET)
- C. Data Conversion Laboratories webinar (February 23, 1:00 – 2:30 pm ET)

D. FDA webinars and in-person meetings

1. [Industry training](#)
2. [Vendor training](#)

E. Generics Sub-team teleconference (January 13, 2009, 1:00 pm ET)

Representatives from Dun & Bradstreet (D&B) will be on the call.

F. ex pharma Conference: Emerging Global Electronic Submission Standards* (January 22-23, 2009, National Harbor, MD).

*This is provided for information only and does not imply any endorsement or recommendation of the organization or event.

VI. Other

A. Graphics must be submitted as jpg files. Submissions in pdf format will be rejected.

B. There was a question posed by a sub-team member for which a reply has been received (not discussed during the call).

Question: This statement was published in the Federal Register Guidance for Industry Indexing Structured Product Labeling dated June 2008, page 6 of 7.

"Content of labeling refers to all text, tables, and figures associated with the prescribing information. It does not include carton and immediate container labels."

I was wondering if it is correct regarding the labeling text for SPL OTC format or if this was just true for Rx Inserts (Package Inserts).

Do the label Mechanicals (panels) for OTC Drugs need to be included as J-pegs in the SPL OTC format?

Answer: The indexing SPL guidance document is not related to the drug establishment registration and drug listing SPL draft guidance document. Regarding the inclusion of carton and container labels for OTC drug products, one should utilize the drug establishment registration and drug listing draft guidance document as an information source.

VII. Vendor Presentation: i4i

The vendor presentations are provided as educational opportunities only and do not reflect any endorsement or recommendation by the SPL OTC Sub-team, SPL Process Team, SPL Leadership Team, or the FDA.

Slides from the presentation are now available at the Wiki page at the OTC sub-team site.

MDH/01-12-09

SPL OTC Sub-team call 12 January 2009 011209.doc

Last Revised: January 14, 2009 Sent: January 14, 2009

Mass Delisting Procedures – From Generics SPL Sub-team Minutes of December 15, 2008

(please visit Wiki page for additional information)

How to mass delist prior to the date when the electronic submission of drug establishment registration and drug listing information is mandatory.

This discussion is about NDC delisting. This would be to clean up NDC lists and avoid having to submit the SPL just to have it removed.

The information the FDA needs is:

- Name of drug
- Strength & unit
- Discontinuation date (may be future dated)
- NDC Number

The above is sufficient to remove NDC numbers from the NDC database. You may put in an Excel spreadsheet with the above information and send it to: spl@fda.hhs.gov **prior to June 1, 2009.**